

In the United States Court of Federal Claims

No. 13-675V

(Filed Under Seal: August 9, 2017)

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BO DEPENA and NATALIE DEPENA, *
legal representatives of a minor child, R.D., *

Petitioners, *

v. *

SECRETARY OF HEALTH AND *
HUMAN SERVICES, *

Respondent. *

Vaccine Act; Motion for Review; MMR
Vaccine; Severe Pneumonia; Althen;
Causation-in-Fact; Consideration of Medical
Literature; Expert Credibility

Michael Baseluos, San Antonio, TX, for petitioners.

Heather L. Pearlman, United States Department of Justice, Washington, DC, for respondent.

OPINION AND ORDER

SWEENEY, Judge

Petitioners Bo and Natalie DePena seek compensation under the National Childhood Vaccine Injury Act of 1986 (“Vaccine Act”), 42 U.S.C. §§ 300aa-1 to -34 (2012), alleging that their son, R.D.,² developed severe pneumonia as a result of a Measles-Mumps-Rubella (“MMR”) vaccination. In a February 22, 2017 decision, the special master denied petitioners’ request for compensation. Before the court is petitioners’ motion for review of the special master’s decision. For the reasons set forth below, the court denies petitioners’ motion and sustains the decision of the special master.

¹ Vaccine Rule 18(b), contained in Appendix B of the Rules of the United States Court of Federal Claims (“RCFC”), affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute “a clearly unwarranted invasion of privacy.” Neither party objected to the public disclosure of any information contained in this opinion.

² Because R.D. is a minor, the court will refer to him by his initials. See RCFC 5.2(a).

I. BACKGROUND

A. R.D.'s Medical History

R.D.'s medical history, which is undisputed by the parties, can be briefly summarized.³ R.D. was born in 2003. He received his first MMR vaccination in August 2004. He also received three pneumococcal conjugate vaccinations—which protected against seven strains of Streptococcus pneumoniae (“pneumococcus”)—in November 2003, March 2004, and June 2005.

On September 15, 2010, during an appointment with his pediatrician, R.D. received several vaccinations, including a second MMR vaccination. Two days later, R.D.'s mother reported that R.D. had a bad reaction to the vaccinations, and there is photographic evidence of raised dots on R.D.'s thigh. Then, on September 25, 2010, petitioners took R.D. to the emergency room because he was experiencing lower back pain; R.D. also had a two-day history of cough and a higher-than-normal temperature. The emergency room doctors diagnosed an acute viral syndrome.

Because R.D.'s health did not improve, his mother took him to his pediatrician on September 28, 2010. R.D. had a high fever, his skin had a grayish color, and he made grunting sounds when breathing. A chest x-ray revealed bilateral pneumonia. R.D. was admitted to the hospital. During the hospitalization, R.D.'s physicians determined that pneumococcus was the cause of R.D.'s pneumonia. They further determined, after testing R.D.'s blood for the presence of antibodies against fourteen serotypes (i.e., strains) of pneumococcus, that R.D. had protective levels of antibodies for only three serotypes. Due to the severity of his pneumonia, R.D. remained hospitalized for twenty-one days, and ultimately was discharged on October 18, 2010.

In the years following his discharge from the hospital, R.D. was diagnosed with mild reactive airway disease and prescribed an inhaler, a CT scan revealed slight scarring in R.D.'s chest, and a spirometry test was normal. By 2016, R.D.'s condition had improved. Moreover, even though testing conducted in 2016 revealed that R.D. did not have protective levels of antibodies for thirteen serotypes of pneumococcus, he had not suffered from any episodes of pneumonia since his 2010 hospitalization.

B. Medical and Scientific Background

In their motion for review, petitioners contend that the special master erred by rejecting their theory that R.D.'s September 15, 2010 MMR vaccination caused R.D.'s severe pneumonia. However, neither they nor respondent contests much of the medical and scientific background

³ The court derives this information from the special master's decision. See generally DePena v. Sec'y of HHS, No. 13-675V, 2017 WL 1075101, at *2-6 (Fed. Cl. Spec. Mstr. Feb. 22, 2017).

information contained in the special master's decision. Because this information provides context for the arguments set forth in petitioners' motion for review, the court briefly recounts it.

1. Operation of the Immune System

As an initial matter, the special master provided a basic explanation of the immune system:

A body's responses to foreign invaders, often called antigens or pathogens, are controlled by the immune system. Immunologists generally divide the immune system into two branches: the innate immune system and the adaptive immune system.

Innate Immune System. The innate immune system is relatively primitive. The innate immune system generally recognizes foreign invaders. Components of the innate immune system include cytokines, natural killer cells, and complement.

. . . .

Adaptive Immune System. In comparison to the innate immune system, the adaptive immune system is more advanced. The adaptive immune system recognizes specific antigens. The adaptive immune system contains two types of cells: B cells and T cells. . . .

B cells. B cells make antibodies. Antibodies, in turn, can be classified into different types of immunoglobulin. Antibodies recognize polysaccharides (or sugars). Antibodies' ability to respond to polysaccharides is one trait that distinguishes them from T cells.

T cells. The other part of the adaptive immune system is T cells. T cells derive their name from the thymus, where they mature.

T cells are further classified. The basic division is into two groups, known as cytotoxic T cells and helper T cells. Cytotoxic T cells, which are also known as CD8⁺ cells, kill cells that are infected by viruses. . . .

There are multiple types of helper T cells, also known as CD4⁺ cells. Th1 cells help cytotoxic T cells kill cells infected with infectious agents, especially viruses. Th2 cells help B cells. Th17 cells help cells at the mucosal level respond to infections Another type of helper T cell makes sure that the immune

system does not overrespond. These helper T cells are known as T regulatory cells.

DePena, 2017 WL 1075101, at *5-6 (footnotes and citations omitted).

2. The MMR Vaccine and the Measles Virus

The special master also provided information regarding the MMR vaccine and the measles virus:

The MMR vaccine is an attenuated vaccine, that is, the vaccine contains a weakened form of the live measles virus. In its wild (or natural) state, the measles virus is extremely virulent. Measles causes the death of thousands of unvaccinated people each year.

The people who survive measles infection are more vulnerable to infection from other pathogens for 1-4 weeks. Scientists have recently theorized that the measles virus destroys the memory aspect of the survivor's immune system. Without this memory in their immune system, survivors of the measles virus may be unable to fight off infection and may contract diseases.

Id. at *4. He further explained "that the MMR vaccine can have the same consequence as the wild measles virus: a suppression of some parts of the adaptive immune system." Id.

3. Pneumococcus

Finally, the special master described pneumococcus and how the body can react to it:

Pneumococcus is a type of bacterium. There are more than 90 strains of pneumococcus and the numerous strains contribute to the difficulty in developing an effective vaccine. The outside capsule of pneumococcus is comprised of polysaccharides. Polysaccharides are carbohydrates, like sugars. When faced with a polysaccharide invader, the body's adaptive immune system responds by producing antibodies, which come from B cells, and the body does not produce T cells in response. Consequently, pneumococcus has been categorized as a type II T cell-independent antigen.

The body's encounter with pneumococcus is unusual in the sense that the first step is colonization. Colonization means that a strain of pneumococcus is living in a person's nose and throat. This nasopharyngeal colonization is extremely common with estimates exceeding 25 percent. Colonization, which is also known as carriage, is especially frequent in the very young and the very old.

During colonization of the mucosal surfaces of the nose and throat, the body's adaptive immune system produces an antibody known as immunoglobulin A. On some occasions, and in some people, a colonization resolves without a worsening of symptoms.

However, pneumococcus can also migrate from the nasopharynx to other portions of the body. . . . [R]elatively little is known about how this change occurs. When pneumococcus moves to the ears and sinuses, it causes otitis media and sinusitis. These types of infections are both relatively common and mild. It is much more alarming when pneumococcus infects the lungs, causing a condition called pneumococcal pneumoniae.

In the United States in 2015, more than one million people suffered from pneumococcal pneumoniae.

Id. at *3 (citations omitted). He further noted that “the innate immune system contributes to how the body responds when pneumococcus becomes infectious.” Id. at *5.

II. PROCEDURAL HISTORY

Petitioners filed a petition for compensation under the Vaccine Act on September 12, 2013. Upon reviewing R.D.'s medical records, respondent recommended that the special master deny petitioners compensation. Thereafter, the parties submitted expert reports. Petitioners ultimately provided the special master with six submissions—five reports and a response to a legal brief—from pediatric pulmonologist Boris M. Lokshin, M.D., and respondent provided three reports from pediatric immunologist Neil D. Romberg, M.D. The special master convened an evidentiary hearing,⁴ during which he heard the testimony of Dr. Lokshin and Dr. Romberg. The parties offered posthearing submissions, and the special master issued a decision on February 22, 2017.

In his decision, the special master noted that there was no dispute that R.D. developed severe pneumonia caused by pneumococcus. Rather, the parties disputed whether R.D.'s September 15, 2010 MMR vaccination caused the pneumonia. Petitioners argued, based on the opinion of Dr. Lokshin, that the MMR vaccination impaired R.D.'s immune system's ability to produce T cells, and that the lack of T cells rendered R.D.'s body unable to resist the pneumococcal infection. Respondent countered, based on the opinion of Dr. Romberg, that the MMR vaccination did not affect the parts of R.D.'s immune system responsible for responding to pneumococcal infections and, as a result, the MMR vaccination could not have led to R.D.'s severe pneumonia. In short, the parties disagreed regarding the role that T cells play in responding to a pneumococcal infection; petitioners contended that T cells play a role, while respondent contended that T cells are expendable.

⁴ The hearing occurred over two days—February 11, 2016, and April 12, 2016.

After identifying the parties' dispute, the special master analyzed the viability of petitioners' theory of causation. First, he compared the qualifications of the parties' experts. Dr. Lokshin, the special master noted, was not board certified in immunology, did not have any training in T cells, and was not performing research. The special master qualified Dr. Lokshin as an expert in pediatric pulmonology and declared that Dr. Lokshin "possesse[d] the minimum qualifications to testify about immunologic concepts because of his training and experience." Id. at *8. However, the special master continued:

Dr. Lokshin's lack of specialized training in immunology affected the quality of his testimony. When Dr. Lokshin presented the articles on which he relied, he frequently stated that he was not presenting his opinion, he was simply presenting a view someone else expressed. While it is hornbook law that a testifying expert may rely upon the work of another expert if the testifying expert would normally rely upon the second expert's work, Dr. Lokshin often left the impression that he did not have the depth of experience in immunology necessary to evaluate and render an opinion on immunologic topics.

. . . .

. . . [H]e did not appear fluent in the language of immunology. This lack of fluency, again, gave the impression that Dr. Lokshin had limited experience on which to base his opinions. This impression, in turn, diminished the overall value of Dr. Lokshin's testimony.

Id. at *8-9 (footnote and citations omitted); see also id. at *13 ("Dr. Lokshin . . . seems ill-equipped to topple established immunologic ideas Dr. Lokshin does not routinely treat patients with immunologic disorders, he does not teach classes of medical school students in immunology, he does not have any advanced certifications in immunology, and he does not currently author articles on immunology. In short, when the topic is cutting-edge immunology, Dr. Lokshin has [fewer] qualifications to present new ideas persuasively."). In contrast, the special master credited Dr. Romberg's education and experience in pediatric immunology, and remarked: "Overall, Dr. Romberg's knowledge about immunology was impressive. His demeanor and the content of this testimony demonstrated that he understood how the human immune system functions to a level of great detail. He took care to be precise in his wording." Id. at *10. The special master concluded that "[o]n immunologic topics, Dr. Romberg was, simply, a much stronger witness than Dr. Lokshin." Id.

After evaluating the experts' credentials, the special master discussed three immunological principles related to pneumococcal infections that, he asserted, were not in dispute: (1) "an effective response to pneumococcal infection requires both the innate immune system and antibodies from the adaptive immune system," id.; (2) "T cells do not respond directly to pneumococcal infection," id.; and (3) individuals whose immune systems produce no

B cells or produce defective B cells “do not develop pneumococcal infections” when they receive antibodies, regardless of whether T cells are also present, id. at *13.

The special master then evaluated the proposition at the heart of petitioners’ theory of causation—that a human’s response to pneumococcal infection involves T cells—and the medical literature that petitioners submitted in support of that proposition. Several of the submitted articles described mouse studies, and revealed that mice produce T cells in response to pneumococcal infections. Dr. Lokshin argued that the results of these studies supported a conclusion that humans also produce T cells in response to pneumococcal infections. The special master noted, however, that Dr. Lokshin did not explain the similarities between mice and humans that would support extrapolating the results of the studies from mice to humans, and that Dr. Romberg testified—and provided supporting evidence—that “with respect to the response to pneumococcal infections, mice differ from people.” Id. at *14. The special master concluded that “[w]ithout some reliable showing that an extrapolation from mice to people is appropriate, the studies based upon mice are not useful.” Id.

Petitioners also submitted articles that described studies in humans, as well as other related documents, in support of their proposition that T cells are involved in a human’s response to pneumococcal infection. This evidence reveals that researchers and at least one company are “attempting to develop a vaccine against pneumococcus that stimulates the production of T cells,” and “that the National Institutes of Health has funded research into a T cell based vaccine against pneumococcus.” Id. However, the evidence also reveals that the company suspended development of the vaccine because it was not obtaining statistically significant results; indeed, Dr. Lokshin testified that “research into a T cell based vaccine is ‘just too early’ and ‘not moving as fast’” as desired. Id. at *15. The special master noted:

The goal of developing a T cell based vaccine is certainly laudatory—a successful T cell based vaccine could protect against many (maybe all) strains of pneumococcus. The potential benefits, especially in the regions of the world with less access to medical care, could be immense. However, the worthiness of the pursuit does not automatically make any of [the human] studies a reliable basis for an expert’s opinion.

Id. He therefore concluded that “[t]he articles did not present a persuasive basis for toppling the generally accepted principle in immunology that a human being’s response to a pneumococcal infection does not involve T cells.” Id.

At the close of his decision—after noting that “Dr. Romberg’s opinion was more persuasive than Dr. Lokshin’s opinion” because of “Dr. Romberg’s superior qualifications in immunology, the well accepted and well demonstrated idea that T cells cannot recognize polysaccharides, and the undeveloped effort to overturn immunologic dogma,” id. at *16—the special master analyzed petitioners’ case under the test for causation set forth in Althen v. Secretary of HHS, 418 F.3d 1274 (Fed. Cir. 2005). In Althen, the United States Court of

Appeals for the Federal Circuit (“Federal Circuit”) articulated a three-part test, based on prior precedent, explaining what a petitioner must show to prove causation under the Vaccine Act:

[Petitioner]’s burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. at 1278. The special master concluded that petitioners had not established either of the first two prongs of the Althen test, explaining that petitioners had not reliably shown “that T cells have a substantive role in a human being’s response to a pneumococcal infection.”⁵ DePena, 2017 WL 1075101, at *16. Moreover, with respect to the second prong of the Althen test, the special master further noted that none of R.D.’s treating physicians posited that R.D.’s severe pneumonia was the result of his September 15, 2010 MMR vaccination; that R.D.’s case did not fit within the challenge-rechallenge paradigm (when an individual who reacts to the administration of a vaccine exhibits a more severe reaction to a second administration of that vaccine); and that R.D.’s persistent low levels of antibodies protective against pneumococcal infection and concomitant failure to develop a second pneumococcal infection did not mean that R.D.’s September 15, 2010 MMR vaccination—which triggered a decrease in T cells—was the only event that could have caused R.D.’s severe pneumonia because “isolat[ing] the MMR vaccination and consequent decrease in T cells as the reason for [R.D.’s] pneumococcal pneumonia seem[ed] to overlook many other potentially contributory factors.” Id. at *18. He therefore denied petitioners’ request for compensation. Petitioners, alleging error, seek review of the special master’s decision, which respondent opposes. Upon reviewing the record that was before the special master and hearing the parties’ arguments, the court is prepared to rule.

III. DISCUSSION

The United States Court of Federal Claims (“Court of Federal Claims”) has jurisdiction to review the record of the proceedings before a special master, and upon such review, may:

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

⁵ Respondent conceded that the third prong of the Althen test had been satisfied.

42 U.S.C. § 300aa-12(e)(2). The standards set forth in section 12(e)(2)(B) “vary in application as well as degree of deference. . . . Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard.” Munn v. Sec’y of HHS, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

In the instant case, petitioners enumerate, pursuant to Vaccine Rule 24, three objections to the special master’s decision. First, petitioners contend that the special master failed to seriously consider the medical literature supporting their theory of causation. Second, petitioners assert that the special master improperly relied solely on an assessment of expert credibility in rejecting their theory of causation, impermissibly raising their burden of proof. Third, petitioners aver that the special master erroneously determined that they could not causally link R.D.’s September 15, 2010 MMR vaccination to his severe pneumonia. In short, petitioners believe that they have established a *prima facie* case of causation under the Vaccine Act.

A. Proving Causation Under the Vaccine Act

Pursuant to 42 U.S.C. § 300aa-13(a)(1), the court shall award compensation if a petitioner proves, by a preponderance of evidence, all of the elements set forth in 42 U.S.C. § 300aa-11(c)(1),⁶ and if there is not a preponderance of evidence that the illness is due to factors unrelated to the administration of the vaccine. A petitioner can recover in one of two ways: either by proving an injury listed on the Table or by proving causation-in-fact. See 42 U.S.C. §§ 300aa-11(c)(1)(C), -13(a)(1). Under the first method of recovery, a petitioner must demonstrate that the injury was sustained within the time frame set forth in the Table. Id. § 300aa-11(c)(1)(C)(I), -14(a). “If petitioner can make such a showing, causation is presumed and petitioner is deemed to have made out a *prima facie* case of entitlement to compensation under the Act.” Whitcotton v. Sec’y of HHS, 81 F.3d 1099, 1102 (Fed. Cir. 1996).

To establish a *prima facie* case when proceeding on a causation-in-fact theory, as petitioners attempted to do in this case, a petitioner must “prove, by a preponderance of the evidence, that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury.” Shyface v. Sec’y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

⁶ Subsection (c)(1) requires, among other things, that the following elements be satisfied: (1) that the vaccine in question is set forth in the Vaccine Injury Table (“Table”); (2) that the vaccine was received in the United States or in its trust territories; (3) that the injured person either sustained an injury as a result of the administration of a Table-designated vaccine for a period of more than six months after the administration of the vaccine, suffered illness, disability, injury, or condition from the vaccine that resulted in inpatient hospitalization and surgical intervention, or died from the administration of the vaccine; and (4) that the petitioner has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine-related injury or death. 42 U.S.C. § 300aa-11(c)(1).

“[T]o show that the vaccine was a substantial factor in bringing about the injury, the petitioner must show ‘a medical theory causally connecting the vaccination and the injury.’” Id. at 1352-53 (quoting Grant v. Sec’y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (per curiam)). In other words, “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury,’” id. at 1353 (quoting Grant, 956 F.2d at 1148), and “[t]his ‘logical sequence of cause and effect’ must be supported by a sound and reliable medical or scientific explanation,” Knudsen v. Sec’y of HHS, 35 F.3d 543, 548 (Fed. Cir. 1994) (citing Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993); Jay v. Sec’y of HHS, 998 F.2d 979, 984 (Fed. Cir. 1993)); accord Grant, 956 F.2d at 1148 (“A reputable medical or scientific explanation must support this logical sequence of cause and effect.”); see also 42 U.S.C. § 300aa-13(a)(1) (“The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.”). However, medical or scientific certainty is not required. Knudsen, 35 F.3d at 548-49; Bunting v. Sec’y of HHS, 931 F.2d 867, 873 (Fed. Cir. 1991).

As noted above, the Federal Circuit, in Althen, distilled this prior precedent into a three-part test, holding that to prove causation-in-fact, a petitioner must provide “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” 418 F.3d at 1278. All three prongs “must cumulatively show that the vaccination was a ‘but-for’ cause of the harm, rather than just an insubstantial contributor in, or one among several possible causes of, the harm.” Pafford v. Sec’y of HHS, 451 F.3d 1352, 1355 (Fed. Cir. 2006).

The Federal Circuit also explained in Althen that causation-in-fact can be established with circumstantial evidence—in other words, with medical records or medical opinion. 418 F.3d at 1279-80 (citing 42 U.S.C. § 300aa-13(a)(1)). A petitioner “need not produce medical literature or epidemiological evidence to establish causation,” but “where such evidence is submitted, the special master can consider it in reaching an informed judgment as to whether a particular vaccination likely caused a particular injury.” Andreu v. Sec’y of HHS, 569 F.3d 1367, 1379 (Fed. Cir. 2009); see also id. at 1380 (remarking that a special master may assess “the relevant scientific data” when determining whether a petitioner has offered a reputable and reliable explanation supporting his theory of causation); Capizzano v. Sec’y of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006) (“[R]equiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen[, and] impermissibly raises a claimant’s burden under the Vaccine Act . . .”). But see LaLonde v. Sec’y of HHS, 746 F.3d 1334, 1341 (Fed. Cir. 2014) (“In Vaccine Act cases, petitioners must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation under the preponderance of the evidence standard. The level of specificity of such support may vary from circumstance to circumstance.”).

Once a petitioner has established a prima facie case, the burden shifts to the respondent to show, by a preponderance of the evidence, that the injury was caused by a factor unrelated to the vaccine. 42 U.S.C. § 300aa-13(a)(1)(B); Shalala v. Whitecotton, 514 U.S. 268, 270-71 (1995); Deribeaux v. Sec’y of HHS, 717 F.3d 1363, 1367 (Fed. Cir. 2013). However, if a petitioner fails to establish a prima facie case, the burden does not shift. Bradley v. Sec’y of HHS, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Regardless of whether the burden ever shifts to the respondent, the special master may consider the evidence presented by the respondent in determining whether the petitioner has established a prima facie case. See Stone v. Sec’y of HHS, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (“[E]vidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); de Bazan v. Sec’y of HHS, 539 F.3d 1347, 1352 (Fed. Cir. 2008) (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner’s evidence on a requisite element of the petitioner’s case-in-chief.”).

B. Petitioners Have Not Established That the Special Master Erred in Considering the Medical Literature That They Submitted

In their motion for review, petitioners first challenge the special master’s consideration of the submitted medical literature. In particular, they argue that a “cursory review,” Mot. 9, of a sample of fifteen of the articles they submitted supports their theory that “the absence of [the] protection provided by antibodies” does not automatically result in the development of a pneumococcal infection and that “[n]atural protection from pneumococcal infection in those without ready to use specific antibodies is very much T cell dependent,” id. at 8. See also id. at 12 (“The articles cited by Petitioners, even under the most cursory of reviews, reasonably stand for the proposition that T cells play a substantial role in the modulation and prevention of invasive pneumococcal disease.”). By failing to properly consider this evidence, petitioners argue, the special master “impermissibly raised [their] burden under Althen prong one from a reputable medical theory in which T cell suppression from MMR vaccine can substantially play a role in the development of [invasive pneumococcal disease] to one of medical and scientific certainty.” Id. at 12. Respondent, in contrast, contends that the special master’s decision reflects that the special master reviewed all of the medical literature in the record, including the medical literature submitted by petitioners, and properly determined that the medical literature did not support petitioners’ theory of causation.

Under the Vaccine Act, “a special master, reviewing the entire record of the case before him, must consider all relevant medical and scientific evidence contained in the record,” and “‘shall’ consider the entire record, which includes this relevant evidence, when assigning the weight given to particular evidence.” Moriarty v. Sec’y of HHS, 844 F.3d 1322, 1327-28 (Fed. Cir. 2016). Moreover, reviewing courts generally presume that a special master has considered all of the material in the record, regardless of whether it is mentioned in his or her decision. Id. at 1328; Hazlehurst v. Sec’y of HHS, 604 F.3d 1343, 1352 (Fed. Cir. 2010). In his decision, the special master referenced and discussed many of the articles submitted by the parties by name.

See DePena, 2017 WL 1075101 *passim*. He also specifically declared that he had reviewed all of the submitted medical literature. See *id.* at *1 (“The undersigned has reviewed all [of petitioners’] articles. . . . The undersigned has reviewed all [of respondent’s] articles as well.”), *9 (“[T]he undersigned has reviewed all the articles”). Thus, petitioners do not attempt to rebut the presumption that the special master considered all of the submitted medical literature. Rather, their argument is focused on the weight that the special master assigned to the articles that they submitted.

Special masters “have very wide discretion” in determining what evidence to consider and “the weight to be assigned that evidence.” Whitecotton, 81 F.3d at 1108; accord Koehn v. Sec’y of HHS, 773 F.3d 1239, 1244 (Fed. Cir. 2014) (remarking “that it is within the Special Master’s discretion to weigh the relevant evidence”). Consequently, the court accords deference to the special master’s factual findings and fact-based conclusions, Hodges v. Sec’y of HHS, 9 F.3d 958, 961 (Fed. Cir. 1993), and may not reweigh the evidence, *id.* (holding that “on review, the Court of Federal Claims is not to second guess the Special Master[’]s fact-intensive conclusions”); Hines v. Sec’y of HHS, 940 F.2d 1518, 1527 (Fed. Cir. 1991) (“[A]rguments as to the weighing of evidence . . . do not demonstrate reversible error.”); see also Lampe v. Sec’y of HHS, 209 F.3d 1357, 1363 (Fed. Cir. 2000) (“[W]e do not sit to reweigh the evidence.”); Munn, 970 F.2d at 871 (“[I]t is not then the role of this court to reweigh the factual evidence, or to assess whether the special master correctly evaluated the evidence.”). Indeed, “reversible error is ‘extremely difficult to demonstrate’ if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.’” Lampe, 219 F.3d at 1360 (quoting Hines, 940 F.2d at 1528); accord Hibbard v. Sec’y of HHS, 698 F.3d 1355, 1363 (Fed. Cir. 2012).

According to petitioners, had the special master properly evaluated the medical literature they submitted, he would have concluded that their theory of causation was supported by the necessary “‘indicia of reliability,’” Mot. 12 (quoting Moberly v. Sec’y of HHS, 592 F.3d 1315, 1324 (Fed. Cir. 2010)), and that they had satisfied the first prong of the Althen test. Petitioners’ contention is problematic for two reasons. First, as reflected in his decision, the special master considered the articles submitted by petitioners, but concluded that those articles were outweighed by other evidence in the record. See, e.g., DePena, 2017 WL 1075101, at *12 (“Despite the additional articles providing some evidence to the contrary, Dr. Lokshin conceded that T cells do not respond directly to pneumococcal infection.”), *13-14 (noting that Dr. Lokshin “cited several articles that reported on experiments using mice” but did not make “a reliable showing that an extrapolation from mice to people is appropriate”), *14 (“Dr. Lokshin relied upon human studies to show that a person’s response to a pneumococcal infection involves T cells. . . . The undersigned reviewed this material multiple times and has considered the testimony from both Dr. Lokshin and Dr. Romberg about those articles. The articles did not present a persuasive basis for toppling the generally accepted principle in immunology that a human being’s response to a pneumococcal infection does not involve T cells.”). In other words, the special master considered the relevant evidence, drew plausible inferences, and articulated a rational basis for his conclusion. Second, petitioners’ contention that the special master

improperly considered the evidence in the record amounts to a request that this court reevaluate that evidence. However, the court is not empowered to undertake such a task unless it first concludes that the special master's fact-based conclusions were arbitrary and capricious—and it has not so concluded. In sum, petitioners have not established that the special master failed to properly consider the articles they submitted.

C. Petitioners Have Not Established That the Special Master Solely Relied on an Assessment of Expert Credibility

In their second objection to the special master's decision, petitioners contend that the special master relied solely on his assessment of the credibility of the testimony of the parties' experts in rejecting their theory of causation, and as a result disregarded the evidence in the record, impermissibly raising their burden of proof. Specifically, petitioners contend that the special master (1) "refus[ed] to apply the results of mouse studies to human studies," Mot. 13; (2) "essentially disregard[ed] any evidence that T cells respond to pneumococcus," *id.* at 15; (3) ignored a "weakness" with Dr. Romberg's proposition that R.D.'s severe pneumonia was likely caused by a lack of protective antibodies, *id.* at 16; (4) "ignored [the] contradictions" in Dr. Romberg's testimony regarding the role and importance of Th1 and Th17 cells, *id.* at 17; and (5) improperly relied on evidence—a sixty-five-year-old case study of one individual and testimony from Dr. Romberg—regarding the development of pneumococcal infections in individuals with dysfunctional immune systems when "Dr. Lokshin effectively countered" that evidence, *id.* at 18. Respondent, on the other hand, asserts that there was no legal error in either the special master's credibility assessments or the special master's conclusion, based on the evidence in the record, that a human's response to a pneumococcal infection is not dependent on T cells.

Taken as a whole, petitioners' argument is that the special master's determinations regarding the credibility of the parties' experts tainted his consideration of the evidence in the record, causing him to improperly reject evidence supporting their theory of causation and accept evidence that did not support their theory of causation. The Federal Circuit remarked in Andreu that "[w]hile considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review." 569 F.3d at 1379 (citation omitted). The Federal Circuit expanded on these remarks in subsequent decisions:

[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act. . . . In Moberly, we reiterated that a special master may not cloak the application of an erroneous legal standard in the guise of a credibility determination to shield it from appellate review. We went on to clarify that this does not mean that "a special master, as the finder of fact in a Vaccine Act case, is prohibited from making credibility determinations regarding

expert testimony.” We indicated that “[a]ssessments as to the reliability of expert testimony often turn on credibility determinations” and “[f]inders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence.” Our discussion of the issue in Broekelschen is equally clear.⁷ In that case, we recognized that “[e]xpert medical testimony is often very important in Vaccine Act cases based on off-Table injuries requiring proof of actual causation.” We again explained that “the special master’s decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories” and such credibility findings “are virtually unchallengeable on appeal.” Finally, in Doe,⁸ we upheld a special master’s factual findings as not arbitrary and capricious “particularly in light of the credibility findings made as to the parties’ respective experts.” We found no basis for disturbing the special master’s credibility findings as to those experts, and again emphasized that “the special master’s unique position to see the witnesses and hear their testimony” makes “such credibility assessments . . . ‘virtually unreviewable on appeal.’”

Porter v. Sec’y of HHS, 663 F.3d 1242, 1250-51 (Fed. Cir. 2011) (footnotes added) (citations omitted).

As an initial matter, the special master was entitled to assess the credentials of the parties’ experts as a means of assisting his evaluation of the experts’ reports and testimony. Id. He was also entitled to gauge the credibility of the experts through a review of their reports and testimony. Id. Applying the deferential standard of review that is required in such circumstances, the court finds no error in the special master’s determination that Dr. Lokshin was a less credible expert witness than Dr. Romberg on immunological topics. The special master thoroughly reviewed the experts’ educational and professional backgrounds, and properly assessed the experts’ understanding of both the relevant immunological concepts and the relevant medical literature. In short, there is nothing arbitrary or capricious in the special master’s credibility determinations.

Petitioners complain that by concluding that Dr. Lokshin was less suited than Dr. Romberg to render opinions on the immunological issues implicated in this case, the special master erroneously disregarded both the evidence that Dr. Lokshin relied upon in advancing petitioners’ theory of causation and the flaws in Dr. Romberg’s opinion and evidence. However, as repeatedly recognized by the Federal Circuit, special masters are entitled to use their credibility assessments to inform their conclusions regarding whether a petitioner has offered a reputable and reliable explanation supporting his or her theory of causation. Id. In this case, the

⁷ Broekelschen v. Sec’y of HHS, 618 F.3d 1339 (Fed. Cir. 2010).

⁸ Doe 11 v. Sec’y of HHS, 601 F.3d 1349 (Fed. Cir. 2010).

special master did not use his credibility determinations as an excuse not to evaluate the evidence in the record. Rather, he evaluated the evidence keeping in mind the experts' credentials and understanding of the pertinent immunological topics, and thoroughly explained his reasons for crediting or discounting the evidence. The five purported errors highlighted by petitioners do not demonstrate otherwise.

First, with respect to the mouse studies relied upon by petitioners, the special master discussed the studies, the experts' testimony regarding the studies, Dr. Lokshin's failure to explain how humans and mice are similar, and the evidence suggesting that the results of mouse studies cannot be applied to humans before concluding that "[w]ithout some reliable showing that an extrapolation from mice to people is appropriate, the studies based upon mice are not useful." DePena, 2017 WL 1075101, at *14. Second, with respect to whether T cells can respond to pneumococcus, the special master discussed the relevant medical literature and the experts' testimony, and explained that Dr. Lokshin conceded that "pneumococcus is a T cell independent antigen" and that "T cells do not respond directly to pneumococcal infection." Id. at *12. Third, with respect to petitioners' suggestion that Dr. Romberg erroneously posited that R.D.'s severe pneumonia was likely caused by a lack of protective antibodies, the special master—referring to two of Dr. Romberg's reports and his hearing testimony—explained that petitioners had misconstrued Dr. Romberg's opinion: "Dr. Romberg listed parts of the innate immune system, such as complement, as contributing to the protection against pneumococcal infection." Id. at *18; accord id. at *5 (noting Dr. Lokshin's agreement with Dr. Romberg's opinion that "the innate immune system contributes to how the body responds when pneumococcus becomes infectious"), *10 (quoting Dr. Romberg's first report for the proposition that parts of the innate immune system contribute to "human immunity" to pneumococcus). Fourth, with respect to Dr. Romberg's testimony regarding the role and importance of Th1 and Th17 cells, the special master reviewed the articles submitted by petitioners on this topic and petitioners' interpretation of those articles in their posthearing brief, but found the articles unpersuasive in light of Dr. Lokshin's concession that "T cells do not respond directly to pneumococcal infection." Id. at *12. Finally, with respect to evidence presented by Dr. Romberg regarding the development of pneumococcal infections in individuals with dysfunctional immune systems, the special master discussed the relevant medical literature and the experts' testimony, and concluded that such evidence "strongly support[ed] the argument that T cells are expendable in the body's response to pneumococcal infection." Id. at *10.

Ultimately, by flagging these purported errors, petitioners are requesting that this court reevaluate the evidence and draw conclusions that are different from the conclusions reached by the special master. But so long as a special master "has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for" his conclusions, Hines, 940 F.2d at 1528, the court must not reevaluate the evidence, id. at 1527; Lampe, 209 F.3d at 1363; Hodges, 9 F.3d at 961; Munn, 970 F.2d at 871. Here, as reflected in his decision, the special master considered the relevant evidence, drew plausible inferences, and articulated a rational basis for his conclusions. Therefore, petitioners have not established legal error under their second objection.

D. Petitioners Have Not Established That the Special Master Erroneously Concluded That They Failed to Satisfy the Second Prong of the Althen Test

Petitioners' third and final contention is that the special master erroneously determined, under the second prong of the Althen test, that they could not causally link R.D.'s September 15, 2010 MMR vaccination to his severe pneumonia. Specifically, they argue that the special master (1) improperly considered the lack of treating physician opinion supporting a causal link; (2) impermissibly implied that the failure of this case to fit within the challenge-rechallenge paradigm, a possibility raised and ultimately rejected by Dr. Lokshin, weighed against finding a causal link; (3) failed to recognize a flaw in Dr. Romberg's proposition that R.D.'s severe pneumonia was likely caused by a lack of protective antibodies; and (4) improperly offered alternative explanations for R.D.'s development of severe pneumonia.⁹ In response, respondent observes that petitioners' failure to establish that the MMR vaccine can cause severe pneumonia under the first prong of the Althen test means that petitioners cannot demonstrate that R.D.'s September 15, 2010 MMR vaccination did cause R.D.'s severe pneumonia under the Althen test's second prong. Respondent further contends that even if petitioners had satisfied the first prong of the Althen test, the special master did not err in concluding that petitioners had not satisfied the Althen test's second prong. Respondent is correct on both points.

First, to prove causation-in-fact, a petitioner must satisfy all three prongs of the Althen test; a failure to satisfy one prong is fatal to the case. See Pafford, 451 F.3d at 1355; Althen, 418 F.3d at 1278. Because petitioners failed to establish that the special master erred in rejecting their theory of causation, the special master's conclusion regarding the Althen test's second prong is of no moment.

Second, even if petitioners had demonstrated that the MMR vaccine can cause severe pneumonia, their objections to the special master's analysis of the second prong of the Althen test lack merit. The Althen test's second prong requires a petitioner to show "that the vaccine was the 'but for' cause of the harm," Pafford, 451 F.3d at 1356, or, in other words, "that the vaccine actually caused the alleged symptoms in [the] particular case," id. (quoting the decision of the special master as recited by the trial court). To show that the vaccine did cause the injury, a petitioner may, but is not required to, offer evidence of "rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities," or evidence in the form of epidemiological studies. Capizzano, 440 F.3d at 1325. Moreover, the "medical records and medical opinion testimony" of treating physicians can be

⁹ Petitioners also take issue with the special master's "claim[that] the innate system, including complement, contributes to protection against [invasive pneumococcal disease]," Mot. 19, inferring that the special master concluded that a flaw in R.D.'s innate immune system could have led to his development of severe pneumonia. Petitioners' inference is unwarranted. The special master merely stated that R.D.'s "innate immune system could have protected [R.D.] from further pneumococcal infection" in the years following his severe pneumonia. DePena, 2017 WL 1075101, at *18 (emphasis added).

“probative” because “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.” Id. at 1326 (quoting Althen, 418 F.3d at 1278); accord Lombardi v. Sec’y of HHS, 656 F.3d 1343, 1353 (Fed. Cir. 2011); Moberly, 592 F.3d at 1325; Andreu, 569 F.3d at 1375-76. Based on this precedent, the special master did not err in discussing whether a treating physician had opined on the cause of R.D.’s severe pneumonia or whether R.D.’s case fit within the challenge-rechallenge paradigm. Further, as noted above, with respect to petitioners’ contention that Dr. Romberg’s theory of causation was flawed, the special master observed that petitioners had misconstrued Dr. Romberg’s opinion, and the court finds no error in that observation. Finally, the special master did not err in discussing alternative explanations for R.D.’s development of severe pneumonia. Evidence of alternative causes can be used to demonstrate that a petitioner has not established a prima facie case of causation-in-fact, see Stone, 676 F.3d at 1379; de Bazan, 539 F.3d at 1352, and the special master supported his conclusions with evidence from the record. In sum, the special master did not err in concluding that petitioners did not satisfy the second prong of the Althen test.

IV. CONCLUSION

As reflected in his decision, the special master thoroughly reviewed the record before him, fairly considering and weighing the evidence presented by the parties. Thus, for the reasons stated above, the court **DENIES** petitioners’ motion for review and **SUSTAINS** the decision of the special master. The clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

s/ Margaret M. Sweeney _____
MARGARET M. SWEENEY
Judge